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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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858 HAPPY CANYON ROAD SUITE 230			BUI, PHUONG T	
CASTLE ROCK, CO 80108			ART UNIT	PAPER NUMBER
			1638	
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			04/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary		Application No.	Applicant(s)		
		10/552,969	VAN DER HEIDEN, ANTON ARNOLD		
		Examiner	Art Unit		
		Phuong T. Bui	1638		
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1)🖂	Responsive to communication(s) filed on <u>25 Fe</u>	ebruary 2008.			
2a)□	This action is FINAL . 2b)⊠ This	action is non-final.			
3)	☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Dispositio	on of Claims				
5)□ 6)⊠ 7)□	Claim(s) <u>12-31</u> is/are pending in the application ha) Of the above claim(s) is/are withdray Claim(s) is/are allowed. Claim(s) <u>12-31</u> is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or	vn from consideration.			
Application Papers					
 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. 					
Priority u	nder 35 U.S.C. § 119				
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some color None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
2) Notice 3) Inform	(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) No(s)/Mail Date <u>2/3/06</u> .	4) ☐ Interview Summ Paper No(s)/Mai 5) ☐ Notice of Informa 6) ☐ Other:			

Art Unit: 1638

DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's restriction election filed February 25, 2008. Applicant elects Group I without traverse. Claims 12-31 are pending and are examined in the instant application. This restriction is made FINAL.

Information Disclosure Statement

2. A signed and dated copy of Applicant's IDS filed February 3, 2006 is attached to the instant Office action.

Claim Objections

3. Claim 16 is objected to because of the following informalities: "Capsicum" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

- 4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 5. Claims 12-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is an incomplete method claim because it does not result in enhancing the sugar content and/or nutritional value of fruits. Also, the specification defines enhanced nutritional value as "increased concentrations of ascorbic acid". Because those skilled in the art would define enhanced nutritional value differently, it is suggested that Applicant replace "nutritional value" with "concentrations of ascorbic acid". Furthermore, the specification does not define "manipulating". Thus it is unclear

whether "manipulating" means changing the location of the loci or mutating the genes on the loci.

In claim 13 and subsequent claims, "y" and "cf" should be italicized or underlined to indicate these are allele designations.

In claim 14, it is unclear what is retained in the "derived" product. It is suggested that "derived" be amended to "obtained". All subsequent recitations of "derived" are also rejected.

In claim 18, "similar type" is unclear. It is unclear how they are similar and how they are different. Does "similar type" refer to an immature plant of the same genotype, immature plant of a different genotype (which genotype?), or mature plants of a different genotype (which genotype?). All subsequent recitations of "similar type" are also rejected. Applicant is reminded no new matter may be added.

In claim 19, it is unclear which fruits of claim 18 Applicant is referring to. See also claims 20-21 and 24-26.

Claim 27 implies that Evergreen 7181 is the starting product to be used in the method, and not the end product. However, the specification indicates that Evergreen 7181 is the end product. See also claim 28.

Claim 30 should be rewritten as an independent claim because a dependent claim must include all the limitations of the claim it depends from. Here, it is unclear if Applicant wants to specify both the sucrose and ascorbic acid content for claim 30, or Applicant only intents to encompass the "manipulating" step of claim 29, without including the sucrose content.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 112, first paragraph, deposit

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 27-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the plants utilized in the claimed method are essential to the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be readily available to the public. If the plants or their seeds are not so obtainable or available, deposits thereof may satisfy the requirements of 35 U.S.C. 112. The specification does not disclose a reproducible process to obtain the exact same plants/seeds in each occurrence and it is not apparent if such plants/seeds are readily available to the public. If the deposit of the plants/seeds are made under the terms of the Budapest Treaty, then an affidavit or declaration by the Applicant, or a statement by an attorney of record over his or her signature and registration number, stating the plants/seeds have been deposited under the Budapest Treaty and that the plants/seeds will be irrevocably, and without restriction or condition, released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be

Art Unit: 1638

maintained.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and
 - (e) the deposit will be replaced if it should ever become unviable.

Applicant indicated that Evergreen 7181 and Evergreen 6203 are commercially available. However, Applicant does not disclose the source or whether access to them is restricted in any way. A search of the patent literature, non-patent literature and internet does not provide any additional information about these two *Capsicum* cultivars. If Applicant intends to deposit the seeds at the ATCC, providing the ATCC Accession No. and a declaration to indicate compliance with all requirements set forth in 37 CFR 1.801-1.809 would be sufficient to overcome this rejection. Compliance with this

requirement may be held in abeyance until the application is otherwise in condition for an allowance.

Page 6

8. Claims 12-26 and 29-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Evergreen 7181 and Evergreen 6203, does not reasonably provide enablement for "manipulating the CL and Y loci", manipulation to provide two recessive y alleles and two recessive cl alleles, and the claimed sucrose and ascorbic acid levels. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Applicant should note that claims 27-28 are also rejected under 35 USC 112, first paragraph above for failing to comply with the deposit requirements. Claims 27-28 are not included here because this rejection would not apply to claims 27-28 once the deposit requirements have been met.

The breadth of "manipulating the CL and the Y loci" encompasses all possible changes to the loci, most of which will not affect the sugar content or ascorbic acid level of Capsicum. A locus contains many genes. It is highly unpredictable what "manipulation" to what gene(s) would result in the claimed method. Even if the genes were known, it is highly unpredictable what mutation(s)—base additions, deletions, substitutions, and combinations thereof—would result in the claimed method, especially when there is no sequence structure disclosure. The specification states that the Y locus cosegregates with the CSS gene (p. 2). However, this does not address how the Y locus should be manipulated. The specification indicates "The difference between the

Page 7

Y allele and the y allele is a deletion, rearrangement or mutation of a region approximately 25 cM away from the RFLP...marker CT204" (p. 2). However, no direction was given (upstream or downstream) and no specific "deletion, rearrangement or mutation" was shown that would result in enhancement of sugar and ascorbic acid level of fruits. Additionally, the specification states that Applicant has discovered the position of the CL locus and the specific gene involved in the lasting green color phenotype (p. 3). However, Applicant failed to disclose either information. Applicant then contradicts himself by stating "the chromosomal location nor the gene corresponding to the CL locus is known" (p. 6). The working examples show two pepper cultivars with recessive y and cl alleles, presumably obtained through classical breeding. No mutation was shown for any locus. It should be noted that mutations to the CSS gene does not equal to manipulation of the Y locus. Further, Applicant states that the presence of the y allele is indicated by a different sized band on a Southern blot. However, Applicant does not disclose the size of either Y or y allele band. Given the breadth of the claims, the lack of guidance and working examples, the high unpredictability of locus manipulation to result in the desired phenotype, one skilled in the art cannot practice the claimed method as commensurate in scope with the claims without excessive burden and undue experimentation.

With regard to "two recessive *y* alleles and two recessive *cl* alleles", these claims are not enabled for the following reasons. The specification indicates there are at least two loci involved in the color development of fruits of *Capsicum*: Y and CL loci (p. 1). However, it is possible more loci are involved since fruit color is a complex trait; the

sugar content and ascorbic acid level involve multiple biochemical reactions in multiple biosynthetic pathways requiring multiple substrates, enzymes and products; and no genetic analysis was performed on Evergreen 7181 and 6203 to determine its genetic makeup for comparison against other Capsicum cultivars. The art teaches at least 6 loci affecting Capsicum fruit color, not 2 (Newman et al., Plant Physiology, 1989, Vol. 91, pp. 455-458 (U)). Thus, due to the complex nature of these traits, while Evergreen 7181 and 6203 may be homozygous for the recessive y and cl alleles, it is possible that these two cultivars also possess other genetic differences resulting in the above described phenotype. Further, assuming arguendo that only two loci are involved which results in the enhanced sucrose and ascorbic level phenotype, Applicant provided no guidance as to how to make and select plants which are homozygous for recessive y and cl alleles (see preceding paragraph). Accordingly, Applicant has not enabled the claimed method for obtaining two recessive y alleles and two recessive cl alleles resulting in the above described phenotype.

Page 8

With regard to the claimed sucrose and ascorbic acid levels, the breadth of "at least 1.5 times higher" and "at least 1.3 times higher" has no upper limit. However the 1.5 times and 1.3 times appear to be the upper limit in Applicant's working examples (see Tables 1 and 2). Similarly "more than 5 grams" and "more than 2 grams" have no upper limit. Again, the actual levels obtained are only slightly higher than those cited (see Tables 1 and 2). Additionally, Applicant claims ranges of "5-40 grams" and "5.4 to 16.8 grams" of sucrose. However, the specification shows a range of 5.9 to 6.6, with an SD of 0.5. Similarly, Applicant claims ranges of "2 to 7 grams" and "2.1 to 2.85 grams"

Art Unit: 1638

of ascorbic acid. The specification shows a range of 2.22 to 2.4, with an SD of 0.12. No guidance or working example is provided to show how the higher sucrose or ascorbic acid level can be achieved. It is unpredictable what additional manipulations are required to achieve the claimed levels, since the homozygous recessive alleles *y* and *cl* cannot produce plants having the claimed sucrose and ascorbic acid levels. Thus Applicant has not enabled the claimed levels as commensurate in scope with the claims, and one skilled in the art cannot make and use the claimed invention without undue experimentation.

Remarks

- 9. No claim is allowed.
- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong T. Bui/ Primary Examiner, Art Unit 1638 04/13/08